Catalytica
Pharmaceuticals

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April 14, 1999

Dockets Management Branch, HFA-305
Food and Drug Administration
12420 Parklawn Dr., Room 1-23
Rockville, MD 20857

Re: Docket No. 98D-1267
DRAFT FDA Guidance for Industry on NDA's: Impurities in Drug Substances

To Whom It May Concern:

As a manufacturer and supplier of chemical intermediates, active pharmaceutical ingredients (APIs), and finished drug products to the pharmaceutical industry, Catalytica Pharmaceuticals Inc. supports the above referenced DRAFT FDA Guidance.

We believe that it is imperative that the impurity profile of drug substances be adequately characterized using discerning analytical methods prior to transfer of the manufacturing process to a contract manufacturer. It is incumbent on all drug substance and drug product suppliers to provide this information to manufacturers.

Contract manufacturers must thoroughly understand the impurity profile and stability characteristics of drug substances they manufacture to ensure that any changes are detected prior to product release.

If you should have any questions regarding these comments, please do not hesitate to contact me at (252) 707-7913.

Sincerely,

Beverly G Lewis

Beverly G. Lewis
Manager, Regulatory Affairs

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